BlueCross BlueShield of Louisiana

An independent licensee of the Blue Cross and Blue Shield Association.

Non-Steroidal Anti-Inflammatory Drugs (NSAIDs)

Policy # 00353
Original Effective Date: 06/25/2013
Current Effective Date: 06/18/2014

Applies to all products administered or underwritten by Blue Cross and Blue Shield of Louisiana and its subsidiary, HMO Louisiana, Inc.(collectively referred to as the "Company"), unless otherwise provided in the applicable contract. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

When Services May Be Eligible for Coverage
Coverage for eligible medical treatments or procedures, drugs, devices or biological products may be provided only if:

- *Benefits are available in the member's contract/certificate, and*
- *Medical necessity criteria and guidelines are met.*

Based on review of available data, the Company may consider brand name non-steroidal anti-inflammatory drugs (NSAIDs), (including, but not limited to Celebrex® [celecoxib], Voltaren Gel® [diclofenac sodium], Motrin® [ibuprofen], Mobic® [meloxicam], Flector Patch® [diclofenac epolamine], Pennsaid® topical solution [diclofenac sodium], and Sprix® nasal spray [ketoralac])‡ to be **eligible for coverage** when one of the below patient selection criteria is met:

Patient Selection Criteria
Coverage eligibility will be considered for brand name non-steroidal anti-inflammatory drugs (NSAIDs) when ONE of the following criteria is met:

- There is clinical evidence or patient history that suggests the generically available products will be ineffective or cause an adverse reaction to the patient; OR
- Requested drug is ANY brand name non-steroidal anti-inflammatory drug [NSAID]:
  Patient has tried and failed one generic prescription strength non-steroidal anti-inflammatory drug [NSAID] for the current condition (over-the-counter [OTC] non-steroidal anti-inflammatory drugs [NSAIDs] taken in prescription strength doses do meet this criteria); OR
- Requested drug is a topical brand name non-steroidal anti-inflammatory drug ([NSAID] e.g. Flector Patch, Voltaren Gel, Pennsaid topical solution, Sprix nasal spray):
  Patient has difficulty swallowing or cannot swallow; OR
- Requested drug is Celebrex:
  Patient has documentation of any of the following:
  - Patient is currently taking warfarin or dicumarol; OR
  - Patient has reduced platelet counts or other coagulation disorders; OR
  - Patient is using Celebrex as part of a chemotherapy regimen; OR
  - Patient with an upper gastrointestinal (GI) bleed from a duodenal or gastric ulcer; OR
  - Patient has Familial Adenomatous Polyposis (FAP) OR Attenuated Adenomatous Polyposis Coli (APCC) with adenomatous colorectal polyps

When Services Are Considered Not Medically Necessary
Based on review of available data, the Company considers the use of brand name non-steroidal anti-inflammatory drugs (NSAIDs) when patient selection criteria are not met or for usage not included in the above patient selection criteria to be **not medically necessary.****

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Background/Overview

Non-steroidal anti-inflammatory drugs are approved for use in inflammatory conditions.

Rationale/Source

The patient selection criteria presented in this policy takes into consideration clinical evidence or patient history that suggests the available generic NSAIDs will be ineffective or cause an adverse reaction to the patient. This policy also takes into consideration whether or not a patient is able to swallow, as well as various factors in which the use of a generic NSAID would not be beneficial in comparison to Celebrex. Based on a review of the data, in the absence of the above mentioned caveats, there is no advantage of using a brand name NSAID over the available generic NSAIDs. Generic drugs are considered to have equal bioavailability and efficacy in comparison to brand name drugs.

References

1. Clinical Pharmacology [database online]. Tampa, FL: Gold Standard, Inc.; 2013. Available at http://www.clinicalpharmacology-ip.com/Default.aspx.
2. Arthrotec® tablets [package insert]. New York, NY: Pfizer, Inc; March 2013.
3. Vimovo [package insert]. Cincinnati, OH: Wilmington, DE; March 2014.
4. Duexis® tablets [package insert]. Hunt Valley, MD: Pharmaceutics International, Inc.; October 2013.
5. Flector Patch [package insert]. Piscataway, NJ: Alpharma Pharmaceuticals LLC; February 2011.
6. Voltaren Gel [package insert]. Parsippany, NJ: Novartis Consumer Health, Inc.; October 2009.
7. Pennsaid [package insert]. Hazelwood, MO: Mallinckrodt Pharmaceuticals, Inc.; October 2013.
8. Stanos SP. Topical agents for the management of musculoskeletal pain. J Pain Symptom Manage. 2007;33(3):342-355.
9. Sprix® nasal spray [package insert]. Shirley, NY: American Regent, Inc.; April 2014.
10. Cambia for oral solution [package insert]. Montgomery, AL: Kowa Pharmaceuticals America, Inc.; July 2011.
11. Evers S, Afra J, Frese A, et al. EFNS guideline on the drug treatment of migraine – revised report of an EFNS task force. Eur J Neurol. 2009;16:968-981.
12. Data on file. Alpharma Pharmaceuticals. Received February 18, 2008.
13. Moen MD. Topical diclofenac solution. Drugs. 2009;69(18):2621-2632.
14. Kienzler JL, Gold M, Nollevaux F. Systemic bioavailability of topical diclofenac sodium gel 1% versus oral diclofenac sodium in healthy volunteers. J Clin Pharmacol. 2010;50:50-61.
15. Peniston JH, Gold MS, Alwine LK. An open-label, long-term safety and tolerability trial of diclofenac sodium 1% gel in patients with knee osteoarthritis. Phys Sportsmed. 2011;39:31-38.
16. Jordan KM, Arden NK, Doherty M, et al. EULAR Recommendations 2003: an evidence based approach to the management of knee osteoarthritis: report of a Task Force of the Standing Committee for International Clinical Studies Including Therapeutic Trials (ESCISIT). Ann Rheum Dis. 2003;62:1145-1155.
17. Zhang W, Doherty M, Leeb BF, et al. EULAR evidence based recommendations for the management of hand osteoarthritis: report of a Task Force of the EULAR Standing Committee for International Clinical Studies Including Therapeutics (ESCISIT). Ann Rheum Dis. 2007;66:377-388.
18. Zhang W, Moskowitz RW, Nuki G et al. OARSI recommendations for the management of hip and knee osteoarthritis, Part II: OARSI evidence-based, expert consensus guidelines. Osteoarthritis Cartilage. 2008;16:137-162.
19. American Academy of Orthopaedic Surgeons. Treatment of osteoarthritis of the knee (non-arthroplasty). Full Guideline. December 6, 2008. Available at: http://www.aaos.org/Research/guidelines/OAKguideline.pdf.
20. Richmond J, Hunter D, Irrgang J, et al. American Academy of Orthopaedic Surgeons clinical practice guideline on the treatment of osteoarthritis (OA) of the knee. J Bone Joint Surg Am. 2010;92:990-993.
21. Micromedex® Healthcare Series. Thomson Reuters (Healthcare) Inc. Available at: http://www.thomsonhc.com.
22. Wolfe MM, Lichtenstein DR, Singh G. Gastrointestinal toxicity of nonsteroidal anti-inflammatory drugs. N Engl J Med. 1999;1888-1899.
23. Verdickt W, Moran C, Hantzschel H, et al. A double-blind comparison of the gastroduodenal safety and efficacy of diclofenac and a fixed dose combination of diclofenac and misoprostol in the treatment of rheumatoid arthritis. Scand J Rheumatol. 1992;21:85-91.

24. Ashworth NL, Peloso PM, Muhajarine N, Stang M. Risk of hospitalization with peptic ulcer disease or gastrointestinal hemorrhage associated with nabumetone, Arthrotec®, diclofenac, and naproxen in a population based cohort study. J Rheumatol. 2005;32:2212-7.
25. Lanza FL, Chan FKL, Quigley EMM, and the Practice Parameters Committee of the American College of Gastroenterology. Guidelines for prevention of NSAID-related ulcer complications. Am J Gastroenterol. 2009;104:728-738.
26. Rinder HM, Tracey JB, Souhrada M, et al. Effects of meloxicam on platelet function in healthy adults: a randomized, double-blind, placebo-controlled trial. J Clin Pharmacol. 2002;42:881-886.
27. De Meijer A, Vollaard H, De Metz M, et al. Meloxicam, 15 mg/day, spares platelet function in healthy volunteers. Clin Pharmacol Ther. 1999;66:425-430.
28. Van Kraaij DJ, Hovestad-Witterland AH, De Metz M, et al. A comparison of the effects of nabumetone vs meloxicam on serum thromboxane B2 and platelet function in healthy volunteers. Br J Clin Pharmacol. 2002;53:644-647.
29. Kniff-Dutmer EA, Kalsbeek-Batenburg EM, Koerts J, et al. Platelet function is inhibited by non-steroidal anti-inflammatory drugs but not by cyclo-oxygenase-2 selective inhibitors in patients with rheumatoid arthritis. Rheumatol. 2002;41:458-461.
30. Relafen® tablets [package insert]. Philadelphia, PA: GlaxoSmithKline; February 2006.
31. Schnitzer TJ, Donahue JR, Toomey EP, et al. Effect of nabumetone on hemostasis during arthroscopic knee surgery. Clin Ther. 1998;20:110-124.
32. Kniff-Dutmer EA, Martens A, vd Laar MA. Effects of nabumetone compared with naproxen on platelet aggregation in patients with rheumatoid arthritis. Ann Rheum Dis. 1999;58:257-259.
33. Hochberg MC, Altman RD, April KT, et al. American College of Rheumatology 2012 recommendations for the use of nonpharmacologic and pharmacologic therapies in osteoarthritis of the hand, hip, and knee. Arthritis Care Res. 2012;64:465-474.
34. Derry S, Moore RA, Rabbie R. Topical NSAIDs for chronic musculoskeletal pain in adults. Cochrane Database Syst Rev. 012 Sep 12;9:CD007400.

Policy History

Original Effective Date: 06/25/2013
Current Effective Date: 06/18/2014
06/06/2013 Medical Policy Committee review
06/25/2013 Medical Policy Implementation Committee approval. New policy.
06/05/2014 Medical Policy Committee review
06/18/2014 Medical Policy Implementation Committee approval. Coverage eligibility unchanged.
Next Scheduled Review Date: 06/2015

**Medically Necessary (or "Medical Necessity") - Health care services, treatment, procedures, equipment, drugs, devices, items or supplies that a Provider, exercising prudent clinical judgment, would provide to a patient for the purpose of preventing, evaluating, diagnosing or treating an illness, injury, disease or its symptoms, and that are:

A. in accordance with nationally accepted standards of medical practice;
B. clinically appropriate, in terms of type, frequency, extent, level of care, site and duration, and considered effective for the patient's illness, injury or disease; and
C. not primarily for the personal comfort or convenience of the patient, physician or other health care provider, and not more costly than an alternative service or sequence of services at least as likely to produce equivalent therapeutic or diagnostic results as to the diagnosis or treatment of that patient's illness, injury or disease.

For these purposes, "nationally accepted standards of medical practice" means standards that are based on credible scientific evidence published in peer-reviewed medical literature generally recognized by the relevant medical community, Physician Specialty Society recommendations and the views of Physicians practicing in relevant clinical areas and any other relevant factors.

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